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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|---|---|---|---|---|
| 09/908,943 | 07/19/2001 | Riqiang Yan | 29915 0028 IA U S | 1034 |

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| EXAMINER |
|---|
| PATTERSON, CHARLES L JR |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | |

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/908,943 | YAN ET AL. | |
| | Examiner | Art Unit | |
| | Charles L. Patterson, Jr. | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) *1-20 and 28-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Group 56, claims 21-27 wherein $P_1$ is Y in Paper No. 10 is acknowledged. The traversal is on the ground(s) that there has been no showing that there is a serious burden upon the examiner to examine several of the groups and that the inventions must be independent and distinct. Applicants suggest 8 groups that the invention should be restricted to. This is not found persuasive because it is maintained that it would be a very serious burden upon the examiner to examine all of the groups that applicants suggest combining. The examination of all of groups 1-35 and 73-82 as one group as suggested by applicant would require the search of 52 different specific sequences as well as claims 1 and 21 that are drawn to a multitude of different peptides, claim 1 more so than claim 21. The examiner could have grouped claims 1-19 into many different groups because of all of the possible combinations of different charged, polar, aliphatic of aromatic amino acids in claim 1, but he chose not to in order to simplify the restriction requirement. Each of the peptides of claims 1-35 and 73-82 are structurally different and therefore properly restricted. In addition, claims 1 and 21 are limited to being cleaved by protease molecules of SEQ ID NO:1 or 3 and the examiner could have split these claims and those depending on them into twice as many groups because of this, but he chose not to do so. Claim 1 and dependent claims also are limited to peptides that are not 16 different sequences and the examiner could have split these claims into 16 groups, but he chose not to do so. The examiner also could have had applicant elect one particular SEQ ID NO as their invention and not even taken into account claims 1 and 21 because they involve so many sequences, but he chose not to do this. The search of 52 different sequences would in itself be an unreasonable burden upon the examiner and that doesn't even take into account the search of claims 1 and 21, which read on numerous embodiments.

As to the argument that the groups must be both independent and distinct, in MPEP § 802.01 the meaning of "independent" and "distinct" is discussed, along with a discussion of the legislative history of these terms in patent law. It is concluded in MPEP § 803 that restriction is proper when the inventions "are either independent (MPEP § 806.04 - §806.04(i)) or distinct (MPEP § 806.05 - § 806.05(i))" (emphasis added). The examiner does not agree that in any other jurisdiction and in PCT practice there would be a different restriction requirement or unity of invention requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 and 28-82 and claims 21-27 wherein $P_1$ is not Y are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is apparently incorrect in the recitation of "$P_1$--$P_1$ bind" in line 3 and "$P_1$--$P_1$ bond" on line 4. Apparently the first recitation should be "bond" instead of "bind". There is no "$P_1$--$P_1$ bond" as these are the same residues. Apparently "$P_1$--$P_1$' bond" was intended in each instant.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to millions upon millions of embodiments. The claims are limited to any peptide having 4 or more amino acids meeting the requirements of claim 21 as to what $P_2$, $P_1$, $P_1'$ and $P_2'$ are. This reads on any protein of any length having the limitations of claim 21. The limits are such that when the STIC did the search there were so many hits that it crashed the hard disk and the whole search system. They had to put another limitation into the search to even be able to search the structure of claim 21 and then even they got an extremely large number of hits. Applicants have not enabled the making and/or using of all of the embodiments of the instant claims. Whether or not a particular peptide sequence will be cleaved by the protein encoded by SEQ ID NO:1 or 3 cannot be ascertained by the office and would require obtaining the peptide and testing it with the two proteases. The office does not have facilities to do such testing and must rely upon applicants to do this.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either of Semerjian, et al. (U), Van Camp, et al. (V), Lowell, et al. (W) or Sellar, et al. (X). Semerjian, et al. teach a peptide that contains the sequence DYDA in Fig. 3, the line having "960" at the end, Van Camp, et al. teach a peptide that contains SYDA at positions 132-135 of Fig. 2, Lowell, et al. teach a peptide that contains NYDA a positions 40-43 of Fig. 6 and Sellar, et al. teach a peptide that contains NYDA at positions 40-43 of Fig. 1. The patent office does not have the facilities to test the instant peptides to see if the proteases of the instant claims will cleave these peptides or whether they contain a transmembrane domain, but absent convincing proof to the contrary it is maintained that they do. The addition of a label to aid in the assay would have been obvious. This rejection is being done under 102/103 since it is not known whether the peptides are cleaved by the proteases, but since they meet the requirements of the instant claims as to sequence it is maintained that they are.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
February 14, 2003